

IN THE CLAIMS:

✓
Cancel claims 1-11.

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Amend claim 12 as follows:

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12: (Amended) A surgical irrigator, comprising a pumping unit having an inlet and an outlet, a handpiece and tubing connecting the outlet of said pumping unit to said handpiece, said pumping unit including means for supporting the pumping unit on a pole or the like, a flexible tube connecting at one end to said inlet, and a spike connected to the other end of said flexible tube for connecting said inlet to an irrigation bag, said spike being adapted to penetrate a fitting in said irrigation bag and coated with a lubricant.

REMARKS

Claims 12 and 13 are in this application. Reconsideration of the rejection of these claims under 35 U.S.C. 103(a) is respectfully requested.

Claims 12 and 13 were rejected as unpatentable over Humphreys and Kamen in view of Jepson, the Examiner alleging that it would be obvious to use Kamen's flexible tubing and spike with Humphreys' surgical irrigator and, further, to use silicone or other lubricants for increasing the ease of inserting the spike into the injection site. This rejection is respectfully traversed.

As explained in the specification, this invention is an improvement over the surgical irrigator illustrated and described in Delk, et al. U.S. Patent No. 5,807,313. The '313 patent discloses a battery powered irrigator having a spike at the top of the pumping unit which engages a standard fitting in an irrigation bag. The spike is sized so that the frictional fit with the fitting creates a force sufficient to support the weight of the irrigator. In other words, the high friction fit between the spike and irrigation bag fitting is beneficial; indeed, it is necessary.

Humphreys essentially discloses the same thing although the configuration of the irrigator is different. Because the unit includes the pump, the motor for driving the pump, and the battery for powering the motor, a friction fit is required between the spike and irrigation bag to support the weight of the unit. Although not discussed in the patent, this is deemed advantageous because a separate mechanism is not needed to support the weight of the pump. Kamen has nothing to do with surgical irrigation pumps. Instead, it relates to an intravenous fluid delivery system wherein it is desirable maintain a fluid metering device 3 "within the vertical interval defined by the top and bottom of the reservoir(1)". Since the pump 25 falls beneath the meter 3, obviously the pump cannot be spiked directly into the irrigation bag. The problems and considerations addressed by Kamen do not apply in the case of a surgical irrigation device.

Although applicant believes that claim 12 as originally presented distinguishes patentably over the cited references, claim 12 has been amended to specify that the spike "is adapted to penetrate a fitting in said irrigation bag". This language is intended to clarify the meaning of the term spike by making clear that the spike is not a blunt instrument intended to pass through a slit in an opening in a diaphragm or the like.

The third reference, Jepson, et al., is a lengthy patent which includes 56 figures and a 21 column specification. Jepson also has nothing to do with surgical irrigation devices but relates instead to a two part coupling system for connecting a cannula to the vasculature of a patient. Applicant believes that the portion of Jepson to which the examiner refers is found on column 16, lines 19-24 in which it is stated that the parts of the blunt cannula "are preferably molded of a plastic formulation including silicone or other lubricants. The use of silicone or other lubricant increases the ease of insertion of that member into the pre-slit injection site". Jepson is referring to the insertion of the piercing member 98 through opening 66 in septum 52 (Figs. 3, 4A and 4B). Thus, in the first place, Jepson is talking about the material of the cannula- not coating it with a lubricant. Secondly, and perhaps more important, Jepson is coating a blunt member to ease its insertion through a septum which has been slit at 66. There is no reference to coating a sharp spike or the like which is

intended to pierce a conventional (uncut) fitting or, for that matter, any continuous surface.

With respect to the examiner's specific rejection under section 103, applicants respectfully submit that the proposed combination of Humphreys and Kamen is improper for two reasons. First, Kamen relates to an intravenous fluid delivery system which is entirely different from a surgical irrigator as taught by Humphreys. A person of ordinary skill would not think to modify a surgical irrigation system by reference to an intravenous fluid delivery system. Second, in Humphreys the spike is used to support the weight of the pump. This avoids the need to use a separate holding means to mount the pump on the intravenous pole which saves cost in manufacture and time in setting up the system. It would not be obvious to use a tube and spike in Humphreys since a person of skill in the surgical irrigator field would regard this as a step backwards. Contrary to the examiner's remarks, increasing the length of the tube does not give the patient care provider improved movement during surgery. The purpose of the tube is to enable a pumping unit which is mounted on a pole to be connected to a surgical irrigation bag which is displaced from the pumping unit. To use Kamen's tube in Humphrey's would be regarded as disadvantageous; therefore, the proposed use of Kamen's tube with Humphrey's surgical irrigator can not be deemed obvious.

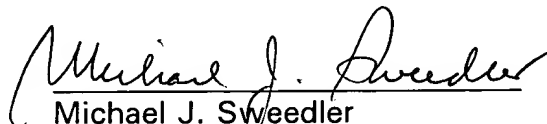
Finally, with respect to the proposed use of a lubricant coating on the spike of Humphreys, it is respectfully noted that Jepson does not disclose a coating; rather, Jepson discloses that the plastic itself may contain a lubricant. Thus, Jepson does not literally teach the claimed use of a lubricating coating although applicants of course, would concede that such coatings are known for many purposes. That fact, however, does not mean that the use of a lubricant on applicants' spike is obvious, which is the test for patentability. In the surgical irrigation field, the spike very often serves as a device for supporting the weight of the pumping unit. Even if it does not fully support the weight, a person of ordinary skill would think that it would generally be beneficial to have the spike at least provide some resistance in order to help secure the pumping unit. Applicants' invention goes against these teachings by reducing the friction between the spike and the irrigation bag so that the spike is incapable of supporting the weight of the pumping unit. Applicants also recognized that the lubricant makes it easier for the nurse or other technician to spike the bag, which has been regarded as a useful feature in assignee's commercial pump.

Applicants recognize that the invention may appear simple but simplicity is not the test for patentability; obviousness is. Lubricating the blunt cannula of Jepson to ease its passage through the opening 66 in septum 62 may be obvious, but lubricating the sharp spike of a surgical irrigator is not. Accordingly, it is respectfully submitted that claims 12 and 13 patentably distinguish over the cited references and

early allowance of this application is respectfully requested.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

A handwritten signature in cursive script, reading "Michael J. Sweedler", is written over a horizontal line.

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PATENT TRADEMARK OFFICE

Docket No: 1780/OF908

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Michael Delk; Augustus Felix

Serial No.: 09/481,120

Art Unit: 3763

Confirmation No.:

Filed: January 11, 2000

Examiner: Sirmons, K.

For: ELECTRICALLY POWERED SURGICAL IRRIGATOR

RECEIVED
MAR 21 2002
TC 3700 MAIL ROOM

**MARK UP FOR AMENDMENT OF MARCH 7, 2002
PURSUANT TO 37 C.F.R. §1.121**

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

March 7, 2002

Sir:

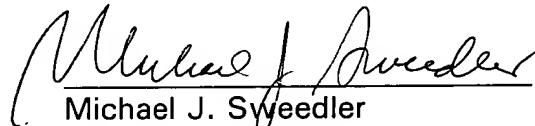
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Respectfully submitted,



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